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09/808,314	03/14/2001	Randall W. Nelson	41821.0236	3078

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/06/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/808,314

Applicant(s)

NELSON ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14, 20-29 and 31-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 20-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II claims 15-19 in Paper No. 10 is acknowledged. Further, Applicant's amendment to cancel elected claims 15-19 and the addition of new claims 31-50 is acknowledged and has been entered.

### ***Oath/Declaration***

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The address of Inventor Krone is crossed out but not initialed and no date of amendment has been disclosed.

### **Specification**

3. The use of the trademark Lumonics HY 400 has been noted in this application on page 41. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. The disclosure is objected to because of the following informalities:

On page 4, line 18 of the specification between the disclosure "field bimolecular" insert --of--.

On page 5, line 26 "quantification" should be --quantitative--.

On page 6, lines 22-23 it is recommended to delete "and is herein incorporated by reference".

On page 17, line 12 it is recommended to insert --, - - after the term nylon.

On page 36 at the end of the second paragraph it is recommended to insert ---.

Appropriate correction is required.

### ***Claim Objections***

5. Claim 37 is objected to because of the following informalities: Claim 37, part (a) the recitation "each the concentration" should be --each of the concentrations--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 41, 49 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 34, 41, 49 and 50 a recitation of "using a micropipette tip in which there is a filter element to which the affinity reagent is bound", but there is no support for this limitation disclosed anywhere in the specification. On pages 40-41 applicant disclose beads having affinity reagent immobilized thereon

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and Applicant discloses slurried affinity reagent incubated with specimen and internal reference. Applicant also disclosed the affinity reagent contains myotoxin a affinity bound to the retain anti-myotoxin a, which was physically separated from the specimen by forcing the volume through the backside of a P-10, 10uL filter pipette tip thereby retaining the affinity reagent on the filter. The applicant does not disclose a filter element to which the affinity reagent is bound. There is no description in the specification disclosing that the affinity reagent is bound to a filter element.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 31-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31, line 1 the recitation "certain" is vague and indefinite. There is no definition provided in the specification for the term and it is unclear what the term is referring to. See deficiencies throughout the claims.

Claim 31, part (a) "constant amount is vague and indefinite. It is unclear if applicant is continuously applying an amount of internal reference species or if applicant intends that a known amount of internal reference species is combined. See deficiencies throughout the claims.

Claim 31, "if the specimen does not already contain one" is vague and indefinite. It is unclear what applicant intends. Was an IRS previously added or does the specimen somehow produce an IRS?

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Claim 32 "effective amount" is vague and indefinite. It is unclear what is considered to be an effective amount. The applicant provides a definition for the term on page 13 of the specification. However, this definition is also vague by disclosing an adequate quantity. Further, it is unclear what result is desired. See deficiency throughout the claims.

Claim 32, part (b) "an unbound remainder" is vague and indefinite. It is unclear if unbound remainder is referring to unbound affinity reagent or unbound analyte or something else. See deficiencies throughout the claims.

Claim 33 "the unique mass-to-charge ratio of the IRS" there is insufficient antecedent basis for this limitation. See deficiency throughout the claims.

Claims 34, 41, 49 and 50 are vague and indefinite. It is unclear if the affinity reagent is bound to the filter prior to the binding to the analyte or if the affinity reagent is bound to the filter after binding to the analyte. Furthermore, there is no support in the specification for an affinity reagent bound to the filter.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claims 31 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaskell et al (Immunoabsorption to Improve Gas Chromatography/High-Resolution Mass Spectrometry of Estradiol-17B in Plasma, Clin. Chem. 29/4, 677-680 (1983)).

Gaskell et al disclose a method for detecting at least one analyte in which an internal standard is added to the sample containing the analyte. Gaskell et al disclose capturing and isolating the analyte and internal standard with an affinity reagent (solid phase antiserum). Gaskell et al disclose that this extract containing the analyte and internal standard is analyzed by GC-MS. Gaskell et al disclose that a standard curve is used for the quantitation of the analyte and internal standard (p 678). Gaskell et al disclose that the standard curve was established by analysis of derivatized standard mixtures.

11. Claims 31-34, and 37-39, 41, and 44-47 are rejected under 35 U.S.C. 102(a) as being anticipated by Nelson et al (Mass Spectrometric Immunoassay, Analytical Chemistry 1995, 67, 1153-1158).

Nelson et al disclose a method to determine an analyte by capturing and isolating an antigen. Nelson et al disclose incubating antibodies covalently immobilized to a solid support with an antigen-containing sample. Nelson et al disclose that after incubation and the formation of antibody/antigen complexes (post-combination affinity reagent), the complexes are washed and then the antigen is eluted onto a mass spectrometer probe tip using a solution of MALDI matrix. Nelson et al. further disclose that after the antigen is eluted that Time-of-flight mass spectrometry is performed (page 1153 col 2, see also Experimental Section). Nelson et al also disclose that a single

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assay can be used to screen biological systems for the presence of multiple, mass-resolved antigens. Nelson et al also disclose combining a reference species to the sample (see Quantitative Analysis Section beginning on page 1156). Nelson et al also disclose that antigen signals are observed at characteristic mass-to-charge values in the mass spectrum. Nelson et al also disclose a plurality of antibodies on a solid substrate (Experimental Section). Nelson et al also disclose that the affinity reagent-antigen complex is retained in a filter pipette tip (Figure 1 and description of Figure 1).

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation



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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 35, 36, 40, 43 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al in view of Papac et al (Direct analysis of Affinity-Bound analytes by MALDI/TOF MS, Analytical Chemistry 194, 66, 2609-2613).

See above for teachings of Nelson et al.

Nelson et al differ from the instant invention in failing to disclose adding a disassociation agent to the isolated post-combination affinity reagent prior to the step of adding the laser desorption/ionization agent.

Papac et al disclose sample preparation can influence the spectra observed when the supernatant is used for analysis (a dissociation reagent is used before application of the desorption/ionization agent) compared with mixing the MALDI matrix with the beads on the target (p. 2613) and that immobilized affinity chromatography differs from conventional chromatography in that it exploits specific biological interactions such as those of an antibody and antigen which demonstrate high specificity associated affinity binding and that, either half of a biological interaction can be used in the stationary phase as an immobilized ligand (p. 2609, paragraph 1).

Papac et al disclose that this dissociation reagent allows for a 3 times stronger signal.

It would have been obvious to one of ordinary skill in the art to incorporate the use of a dissociation reagent as taught by Papac et al into the method of Nelson et al

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because Papac et al show that this dissociation reagent allows for a 3 times stronger signal.

16. Claims 34, 41, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al in view of Raybuck et al (5,833,927).

See above for teachings of Nelson et al.

Nelson et al differ from the instant invention in failing to disclose a filter element to which the affinity reagent is bound.

Raybuck et al disclose a micropipette tip comprising a porous membrane which can act as a filter and also has antibodies bound to the surface for capturing the corresponding analyte (col 5, lines 30-59). Raybuck et al disclose that this membrane provides for a device for capturing a component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment (col 6, lines 26-32).

It would have been obvious to one of ordinary skill in the art to incorporate the substitute the membrane (filter) of Raybuck et al for the filter of Nelson et al because Raybuck et al shows that this membrane provides for a device for capturing a component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment.

#### ***Double Patenting***

17. Claims 31 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim\*\*\* of copending

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Application No. 31-50. Although the conflicting claims are not identical, they are not patentably distinct from each other because although the claims of application 09/808,314 do not require that the IRS is a modified analyte with shifted molecular weight as independent claim 31 in application 09/024,988 one of ordinary skill would recognize that the claims of 09/024,988 would encompass the claims of 09/808,314

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts  
Examiner  
Art Unit 1641  
October 22, 2003



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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10/31/03